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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,978	11/27/2001	Christine Henry	8707.2133	2854

7590 02/12/2004  
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New York, NY 10103-0001

EXAMINER

MACHUGA, JOSEPH S

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/994,978

Applicant(s)

HENRY ET AL.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitzsche et al #5868793 in view of Duncan #5620471.

2.

Nitzsche et al discloses an implantable medical device having means for delivering therapy for the treatment of tachycardia, means for sensing ventricular and atrial activity and means for suspecting and confirming a presence of an episode of tachycardia. Not disclosed by this reference is the means for discriminating between atrial fibrillation with a fast ventricular rhythm and atrial fibrillation and ventricular tachycardia and delivering the appropriate therapy.

Duncan discloses an implantable medical device having means to discriminate between atrial fibrillation with a fast ventricular rhythm and atrial fibrillation and ventricular tachycardia (note column 3, lines 31.) The device (noted the flow chart of figure 2) would also detect the presence of bi-tachycardia and apply the appropriate low energy

shock therapy (also see column 6, lines 31+.) These features would eliminate the application of improper therapy to the patient.

Given Duncan's teaching it would have been obvious to one of ordinary skill in the art to modify Nitzsche et al's device to add the ability to discriminate between atrial fibrillation with a fast ventricular rhythm and atrial fibrillation and ventricular tachycardia to eliminate the application of inappropriate therapy; as well as to detect the presence of Bi-tachycardia and apply the appropriate therapy to the patient.

3. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitzsche et al #5868793 in view of Duncan #5620471 as applied to claim 1 above, and further in view of Kim et al #6047210.

4. Kim discloses an implantable pacemaker having means to measure the amplitude of the P-wave, means to analyze the stability and means to determine the presence of atrial defibrillation (note column 6, lines 45-60.) The reference also includes means to inhibit ventricular activity in response to atrial tachyarrhythmia to avoid complications.

5. Given this teaching, it would have been obvious to one of ordinary skill in the art to add to the proposed combination means to measure amplitude of the P-wave, means to analyze the stability and means to determine the presence of atrial defibrillation and add means to inhibit ventricular activity in response to atrial tachyarrhythmia to provide accurate sensing and to avoid complications.

6. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitzsche et al #5868793 in view of Duncan #562471 as applied to claim 1 above, and further in view of Kim et al #6041251.

Kim et al teaches evaluating the conduction delay between the right and left atrium, analyzing the stability and determining the presence of atrial fibrillation (note the abstract, column 3, lines 16-18, column 5, lines 8+.) The reference also teaches measuring the amplitude of the P-wave, analyzing the stability and determining the presence of atrial fibrillation.


Given this teaching it would have been obvious to one of ordinary skill in the art to modify the device of the proposed combination to include the analysis of the delay between the right and left atrium and the amplitude of the p-wave to provide accurate determinations of atrial fibrillation.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

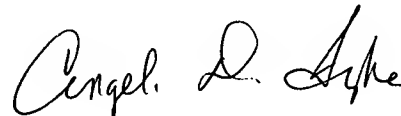
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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